AMERICAN SOCIETY
OF ANESTHESIOLOGISTS

July 30, 2003

David Hyman, Special Counsel
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Mr. Hyman:

This will respond to your request that I provide further written testimony to supplement my presentation at the joint FTC/DOJ hearing on the afternoon of June 10, 2003. I apologize for the tardiness of my response. However, as you know, it took quite some time for me to obtain a videotape of the hearing. I am simply hopeful that this letter arrives in sufficient time to be included in the record with my original presentation.

You expressed particular interest in hearing my further comments on the recent Silber and Pine studies of anesthesia outcomes. Let me say that the greatest deficiency in both these studies is that when the data was collected, Medicare required nurse-administered anesthetics to be supervised by a physician in all cases. Therefore, these studies can compare results only when an anesthesiologist rendered the anesthesia care or when an anesthesiologist or the operating surgeon supervised the anesthesia care. Neither these studies nor any other with which I am familiar present data for patients anesthetized by nurse anesthetists in the absence of supervision by a physician as is currently being sought by the American Association of Nurse Anesthetists.

Also, because both the Pine and Silber studies are based on retrospective and incomplete Medicare billing data, no one can suggest that either study is definitive. As a matter of fact, because its database was insufficient to include them in the analysis, the Pine study eliminated five times as many cases as were reported for nurse anesthetists supervised by non-anesthesiologists.

What is interesting, however, is that both studies – however methodologically limited -- reach the same conclusion, that the death rate is lower when an anesthesiologist is involved in the delivery of anesthesia care than when the supervisor is the operating surgeon. Equally interesting, this conclusion is consistent with conclusions of a number of non-definitive prior retrospective studies. Certainly consistent but limited studies over a period of time do not prove that their common conclusion is correct. They do raise the strong suspicion, however, that there is something here beyond mere coincidence or consistent methodological bias, and when one also appreciates that anesthesiologist involvement means the application of more comprehensive understanding of the science in question, the conclusion becomes entirely credible.

Because of the relatively low overall incidence of anesthesia-related mortality today, it is generally agreed that the only definitive study possible is a randomized prospective study of literally millions of surgical cases. It is doubtful that randomizing which patient will, and which will not, have the benefit of the involvement of an anesthesiologist in such a study would pass ethical guidelines in any

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academic center in this country – so that the best we have and are probably going to have are studies like Silber and Pine. We believe that the intelligent legislative or regulatory course in these circumstances is to require the supervisory involvement of an anesthesiologist, or at least a physician. And we will continue to so advocate.

To be frank, what I found most remarkable about the hearing were the conclusions as to safe anesthesia care offered by a statistician and self-appointed "futurist", Dr. Jeffrey Bauer, who, presumably, has never given an anesthetic in his life. His sole apparent qualification for offering these conclusions was his involvement, ending two decades ago, in helping design the curriculum of students of medicine, nursing and health professions at the University of Colorado Medical School. Dr. Bauer's involvement in anesthesia residency training at Colorado (it does not train nurse anesthetists) was apparently nil: the chairman of that department from 1986 to 2001 had never met nor heard of Dr. Bauer.

Yet Dr. Bauer, as a statistician and futurist, felt qualified at the hearing to make such remarkable statements as "the half-life of a medical education is two years" and "80 percent of what you learned in medical school and residency is not relevant." Leaving entirely aside the fact that any physician would regard these statements as patently absurd – I simply seriously question his qualifications for offering these opinions at all. I know that I, as a practicing anesthesiologist and medical educator, still use many of the basic concepts that I learned in medical school 45 years ago, and I can certainly assure you that the human body's basic physiologic responses to anesthetics, other pharmacological agents, trauma, heart failure, respiratory failure, renal failure, etc., do not change every two years.

Carried to its extreme, Dr. Bauer's thesis as to the lack of continuing importance of a basic anesthesia education would suggest that both anesthesiologists and nurse anesthetists waste their time in medical school and nursing school respectively, as well as in postgraduate formal anesthesia educational programs. He apparently suggests that a more effective alternative would be an on-the-job training course for any mature person exhibiting reasonable scientific acuity. Could it just possibly be that Dr. Bauer, as a paid apologist for the relatively limited basic medical and anesthesia education received by nurse anesthetists, expresses this thesis in order to discount the obvious importance of an anesthesiologist's more comprehensive education and training?

Dr. Bauer's stated conclusion that nurse anesthetists are equal to or even better than anesthesiologists apparently stems from the fact there was a temporary fall-off in the number of medical students entering anesthesia residencies in the mid-1990s, and that average scores on the written Board examination declined later in that decade. The decline in numbers of anesthesiology residents was due to the combination of (1) a faulty study based on an incorrect hypothesis, which predicted a surplus of anesthesiologists by the year 2000, and (2) the channeling by the federal government of graduating medical students into primary care. In fact, there currently is a shortage of anesthesiologists, and Dr. Bauer conveniently fails to note that the number of American medical graduates entering anesthesia residencies has risen sharply in the past three years in response to this shortage. Further, the pass rate for the Board examination is now increasing, and last year returned to the normal prior range.

These facts tell us nothing, however, about the relative qualifications and skills of currently trained anesthesiologists and nurse anesthetists. These two groups of persons enter training with different prerequisites; the content, breadth, depth and duration of their specific anesthesia training is different; and they are evaluated by totally different examination systems.

In his statement, Dr. Bauer also sought to trivialize the requirement, found in Medicare and most state regulations, that a nurse anesthetist be "supervised" by a physician – suggesting that no one understood what the term meant. Leaving entirely aside the fact that Medicare reimbursement regulations closely define the specific elements of medical direction in the anesthesia context, I do not understand why Dr. Bauer has difficulty with the term "supervision": in my dictionary, it means "to oversee, to direct, to manage," and any lawyer will tell you that it carries with it legal responsibility for the acts of the person supervised. The American public certainly understands: in more than a dozen surveys beginning in 1998, two-thirds to three-quarters of Medicare beneficiaries or the American adult population have expressed opposition to the proposal that nurse anesthetists be permitted to render anesthesia care without medical "supervision".

Dr. Bauer cites declining professional liability insurance rates for nurse anesthetists as apparent proof of their increasing quality. What Dr. Bauer omits to note is that anesthesiologist professional liability rates have *also* significantly dropped over the past two decades, and that there is almost always a radical difference in nurse anesthetist rates depending upon whether they are or are not supervised by an anesthesiologist. An anesthesiologist is involved, either as anesthesia provider or supervisor, in 90 percent of the surgeries occurring in this country today. There is absolutely no doubt that the delivery of anesthesia care has become safer today than at any time in the past, but the resulting decline in liability rates tells us nothing about the relative skills of anesthesiologists and nurse anesthetists to practice independently.

During the panel discussion at the end of the hearing, I found myself drawn into discussing the merits of a cost/benefit analysis of the supervision issue. As a physician, I found this discussion extremely discomforting, since, apparently, some would argue that we need only to decide whether the cost of supplying physician supervision is justified in terms of the number of lives it apparently saves. How any representative of government can place a price tag on the cost containment "value" of reducing medical quality standards in terms of lost human lives is beyond my comprehension. Physicians are trained "first, to do no harm" and I find such an analysis ethically repugnant. I am not sure it has any place, moreover, in the agenda of an agency charged with enforcement of the antitrust laws, and I hope you and your colleagues will agree.

Sincerely yours,

Jerome H. Modell, M.D.
JHM/df